

REMARKS

Reconsideration of the present application is respectfully requested in view of the following remarks. Claims 33-86 are pending in the application; claims 73-80 are currently under examination, and claims 33-72 and 81-86 are withdrawn. Applicants thank the Examiner for recognizing the allowable subject matter in claims 79 and 80.

REJECTIONS UNDER 35 U.S.C. § 103

The Examiner rejects claims 73-78 under 35 U.S.C. § 103(a) for alleged obviousness over WO 93/23069 ('069). The Examiner asserts that '069 teaches a composition comprising two or more isoflavone components, including formononetin and biochanin A, but agrees that '069 does not disclose a composition comprising an effective amount of formononetin and biochanin A, wherein the level of biochanin A is about 10% w/w or less of the isoflavone content. The Examiner, however, asserts that in the absence of unexpected results attributable to the particular concentration of formononetin and biochanin as claimed, such a determination would have been made through routine experimentation.

Applicants respectfully traverse this rejection and submit that the instant claims satisfy the requirements of non-obviousness over '069. As previously detailed on the record, Applicants submit that the Examiner has not established that '069 teaches or suggests a composition comprising an effective amount of formononetin and biochanin A, wherein the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less, and has not established that a person skilled in the art at the time of filing would have achieved such a composition for treating menopause with the requisite reasonable expectation of success. See, e.g., *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360, 1363 (Fed. Cir. 2007).

In addition, Applicants respectfully disagree with the Examiner's assertion that achieving the claimed composition for treating menopause could have been made through "routine experimentation" (see the Action, page 3, last sentence, to page 4, first carryover sentence), as that term is utilized in an obviousness inquiry. On this point, it is respectfully submitted that a particular parameter must first be recognized as a result-effective variable, i.e., a

variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. See M.P.E.P. § 2144.05, citing *In re Antonie*, 559 F.2d 618 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal/sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.). Briefly, the Examiner as not established that formononetin represents a result-effective variable for treating menopause, as presently claimed.

In explanation, the subject matter of the instant application is based, in part, on the unexpected discovery that formononetin may be relied upon as the primary compound in an isoflavone-based composition for treating menopause, as recited in the instant claims. Thus, Applicants submit that the Examiner's assertion of obviousness relies on the premise that formononetin represents a result-effective variable for treating menopause. However, similar to *In re Antonie*, in which the cited art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, none of the references of record recognize that treatment or reduction of menopause can be achieved by relying primarily on formononetin. Since the Examiner has not provided any technical evidence or reasoning to support the premise that formononetin represents a result-effective variable for treating menopause, as claimed, which Applicants note must be established before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation, Applicants kindly submit that the Examiner has not satisfied his burden of proof in this regard. See, e.g., *KSR v. Teleflex*, 550 U.S. at ___, 127 S.Ct. 1727, 1741 (2007), citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness cannot be sustained by mere *conclusory statements*; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.") (emphasis added).

In addition, Applicants submit that '069 "teaches away" from relying primarily on formononetin to treat or reduce menopause, as presently claimed. On this point, it is noted that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*,

721 F.2d 1540 (Fed. Cir. 1983); *see also KSR v. Teleflex*, 127 S.Ct. at 1740. A reference “teaches away” when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the Applicants’ invention. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, as previously made of record, ‘069 emphasizes the importance of genistein’s therapeutic biological activities, and de-emphasizes the importance of formononetin, whether for treating menopause or otherwise (*see, e.g.*, ‘069, page 9, paragraphs 5-6). Specifically, ‘069 relies mainly on genistein and daidzein, and teaches that it is prudent that these isoflavones be present in approximately equal proportions (*see, e.g.*, ‘069, page 10, paragraph 3); thereby suggesting that the presently claimed, formononetin-based compounds would have little, if any, therapeutic biological activity. In this regard, ‘069 suggests that the modifications to isoflavone-based compositions described and claimed in the instant application, which heavily favor formononetin, are unlikely to produce the objective of Applicants’ invention, *i.e.*, treating or reducing menopause. Thus, ‘069 teaches away from the instant claims.

In view of the contrary teachings of ‘069, the instant application provides unexpected results with regard to the use of formononetin-based isoflavone compositions for treating menopause. For instance, the instant application teaches that desirable clinical results may be achieved regardless of whether genistein and daidzein are both are present in an isoflavone-related composition, let alone whether these particular isoflavones are present in approximately equal proportions, as taught in ‘069 (*see, e.g.*, Example 6 on page 18 of the specification). Specifically, as compared to the isoflavone compositions of ‘069, the results provided by Applicants demonstrate unexpected therapeutic qualities associated with the use of formononetin for treating or reducing menopause (*see, e.g.*, Examples 6 & 7, on page 18, lines 1-25), which qualities are unexpected and surprising in view of the prior art understanding that demethylation of formononetin improves biological efficacy, and that formononetin has the least activity of all the isoflavones. Indeed, these unexpected results relate, in part, to the observation that formononetin is at all effective in treating or reducing menopause, as compared to the isoflavone compositions of ‘069. Accordingly, the evidence of record not only fails to provide a person of ordinary skill in the art with any apparent reason to formulate a formononetin-based composition with a reasonable expectation of success, as presently claimed, but supports the

non-obviousness of the instant claims by both “teaching away” from the claimed invention, and describing “new and unexpected results relative to the prior art.” See *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

Absent Applicants’ own teachings and results, a person skilled in the art at the time of filing would not have predicted or reasonably expected from ‘069 that an isoflavone composition based primarily on formononetin (*e.g.*, wherein formononetin represents at least about 90% of the isoflavone content) could have been relied upon to treat or reduce menopause, as claimed. This unexpected result can not be found in the cited prior art, and the Examiner has provided no reasonable evidence to suggest otherwise.

Applicants submit that in view of the state of the art at the time of filing, which not only fails to teach or suggest use of an isoflavone composition as claimed to treat menopause, but provides evidence of teaching away from the same, in combination with the lack of evidence and technical reasoning to support the Examiner’s bases for asserting that the instant claims are obvious, Applicants submit that the instant claims satisfy the requirements of non-obviousness over the cited references. Accordingly, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

DOUBLE PATENTING

The Examiner provisionally rejects claims 73-78 for alleged obviousness-type double patenting over claim 1 of co-pending U.S. Application No. 10/611,087 (‘087), which claims foreign priority to WO ‘069, in view of Guggolz *et al.* Similar to the rejection under § 103 detailed above, the Examiner asserts that it would have been obvious to modulate the ratio of formononetin and biochanin A in claim 1 of WO ‘069 to achieve an optimum ration in view of Guggolz *et al.*

Applicants traverse this rejection and submit that the instant claims are non-obvious over the subject matter of claim 1 in the ‘087 application. In particular, claim 1 of the ‘087 application merely recites a generalized isoflavone composition a health supplementary amount of a phyto-oestrogen selected from genistein, daidzein, biochanin A, and/or formononetin. Identical to the rejection under § 103 above, which is incorporated into this

section for brevity, Applicants submit that the Examiner has not established any reason to specifically modulate the isoflavone ratio in favor of formononetin to treat or reduce menopause with a reasonable expectation of success, as recited in the instant claims. For instance, the Examiner has not established that formononetin represents a result-effective variable for treating menopause, which must be established before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. See M.P.E.P. § 2144.05, citing *In re Antonie*, 559 F.2d 618 (CCPA 1977). In this regard, Applicants submit that the Examiner has not established that the instant claims are obvious over claim 1 of the '087 application, whether in view of Guggolz *et al.* or otherwise.

Applicants, therefore, respectfully request reconsideration and withdrawal of this obviousness-type double patenting rejection.

Applicant believes that all of the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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